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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/731,660	12/08/2000	Haruhiko Kouhara	038602/1023	1711

7590

09/21/2004

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EXAMINER

HUTSON, RICHARD G

ART UNIT PAPER NUMBER

1652

DATE MAILED: 09/21/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/731,660	KOUHARA ET AL.	
	Examiner	Art Unit	
	Richard G. Hutson	1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 July 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2,5,6,11-13,20,21,23 and 30-39 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☒ Claim(s) 2, 11-13, 20,21,23 is/are allowed.
- 6) ☒ Claim(s) 5,6 and 30-39 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date. _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicants amendment of claims 5 and 6, the cancellation of claims 4, 22 and 24-29 and the addition of new of claims 30-39, the paper of 7/2/2004, is acknowledged. Claims 2, 5-6, 11-13 and 20, 21, 23 and 30-39 are at issue and are present for examination. Applicants arguments presented on 7/2/2004, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

It is further pointed out to applicants that the newly submitted claims include two claim 37's and no claim 38, and thus the second claim 37 has been changed to claim 38.

Claim Objections

Claim 30 is objected to because of the following informalities:

Newly added claim 30 is drawn to an isolated enriched or purified nucleic acid molecule selected from a number of different groups. Groups (a) and (c) each recite "a nucleotide acid molecule". This should be amended to "a nucleic acid molecule".

Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 30-35 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Newly added claim 30 (claims 31-35 dependent on) is indefinite in that the claims lists a number of parts, (a) through (j) which include specifically described embodiments as well as embodiments drawn to "the complement of such a described nucleic acid", followed by a phrase at the end of the claim limiting the embodiments to those "wherein said FRS-2 polypeptide encoded by the nucleic acid molecules of (a) to (j) binds to Grb-2". It is not understood that if each of parts (a), (c), (e), (g) and (i) are drawn to embodiments with such an activity/function, how the complements of these embodiments, parts (b), (d), (f), (h) and (j), can also have the same embodiment.

Claim 30 is further indefinite in part (i), subparts (1), (2) and (3), in that these subparts are extremely unclear and do not make sense. For instance, part (1) appears to use duplicative language that makes it unclear, part (2) refers to a nucleic acid molecule of (a) that makes it unclear, and part (3) refers to parts (f) and (1), (2), and (3) that makes it unclear.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 5, 6, 30-39 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as

to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The rejection was stated in the previous office action as it applied to claims 4-6, 22, 24 and 25-29. In response to the previous office action applicants have amended claims 5 and 6, cancelled claims 4, 22 and 24-29 and added new claims 30-39 and traverse the rejection as it applies to the newly amended claims. Newly added claims 30-39 are included in this rejection for the reasons previously stated for claims 4-6, 22, 24 and 25-29.

Applicants traverse this rejection on the basis that applicants have amended the claims to replace the term "comprising" with "consisting of", to define that the probe is a fragment of SEQ ID NO: 1 comprising at least specific numbers of amino acids. Applicants further submit that "the Examiner's own SPE, P. Achutamurthy, approved and allowed probe claims 7-12 of U.S. 6,680,170 with similar language as in claim 36". Applicants thus conclude that in view of the amended claim language and the explanation, the rejection should be withdrawn.

Applicants argument in full is acknowledged, however, found non-persuasive for the following reasons. With respect to applicants statement that they have amended the claims to replace the term "comprising" with "consisting of", to define that the probe is a fragment of SEQ ID NO: 1 comprising at least specific numbers of amino acids, applicants attention is drawn to claim 36, which they are presumably referring to. Claim 36 is drawn to a nucleic acid probe "**comprising** of a nucleic acid molecule that **encodes** an amino acid sequence **consisting** of a fragment of SEQ ID NO: 1

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comprising at least 10 contiguous amino acids...” It is unclear as to where exactly applicants have amended the claim from “comprising” to “consisting of” and given the additional wording of the claim how this further helps applicants in their description of the claimed genus, which still uses “open” language.

With respect to applicants statement that “the Examiner’s own SPE, P. Achutamurthy, approved and allowed probe claims 7-12 of U.S. 6,680,170 with similar language as in claim 36”, applicants are reminded that this is a different patent application from the instantly submitted application, with a different fact pattern all together. Thus any submitted similarity between the instant application and the referred to application is not considered appropriate. Regardless applicants submitted “similar language” is unclear, as it appears that the referred to patent claims are not similar to the instantly referred to claim beyond the fact that they are each drawn to a nucleic acid probe that encodes a fragment of a disclosed polypeptide.

Applicant is referred to the revised guidelines concerning compliance with the written description requirement of U.S.C. 112, first paragraph, published in the Official Gazette and also available at www.uspto.gov.

Claims 5, 6, 30-39 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nucleic acid encoding a FRS2 polypeptide, wherein said FRS2 polypeptide has the amino acid sequence of SEQ ID NO: 1, does not reasonably provide enablement for any nucleic acid encoding any FRS2 polypeptide wherein said FRS2 polypeptide merely comprises amino acid residues 1-10 of SEQ ID

NO: 1. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The rejection was stated in the previous office action as it applied to claims 4-6, 22, 24 and 25-29. In response to the previous office action applicants have amended claims 5 and 6, cancelled claims 4, 22 and 24-29 and added new claims 30-39 and traverse the rejection as it applies to the newly amended claims. Newly added claims 30-39 are included in this rejection for the reasons previously stated for claims 4-6, 22, 24 and 25-29.

Applicants traverse the rejection on the basis that while disagreeing with the previous rejection, applicants have cancelled claim 4 and replaced it with new claim 36, which is limited to a nucleic acid probe that encodes an amino acid sequence consisting of a fragment of SEQ IDS NO: 1 comprising at least 10 amino acids and applicants contend that there is adequate written description of the claimed invention and that some of the encompassed embodiments are not long enough to be linked to a function/activity. Applicants further submit that as above, U.S. patent 6,680,170 do not recite such a function.

Applicants argument has been considered in full, however, not found persuasive. With respect to applicants argument based on U.S. Patent 6,680,170, as stated above, this patent is a different patent with a different set of facts and it is not appropriate to discuss the allowed claims of said patent in the current patent prosecution.

With respect to applicants argument that applicants have added new claim 36 as a means of overcoming the previous rejection, claim 36 remains drawn to “a nucleic acid probe **comprising** a nucleic acid molecule that **encodes** an amino acid sequence **consisting** of a fragment of SEQ ID NO: 1, **comprising** at least 10 contiguous amino acids... This claim continues to read on any nucleic acid (or nucleic acid probe) that comprises a nucleic acid that encodes an amino acid sequence consisting of a fragment of SEQ ID NO: 1. The claimed genus remains open based on applicants use of the above **bolded** descriptors and applicants still have only taught that nucleic acid which encodes the amino acid sequence of SEQ ID NO: 1.

With respect to applicants argument that many of the claimed embodiments may not be long enough to encode an FRS2 polypeptide that can be linked to a function/activity, applicants are reminded that as a part of the enablement requirement applicants are required enable the claimed invention with respect to how to **make** and **use** the invention commensurate in scope with these claims. If there is no associated function/activity of the claimed nucleic acid molecules, how have applicants enabled how **to use** such nucleic acids.

Thus, applicants have not provided sufficient guidance to enable one of ordinary skill in the art to make and use the claimed invention in a manner reasonably correlated with the scope of the claims broadly including any nucleic acid encoding any polypeptide comprising a mere 10 contiguous amino acids of SEQ ID NO: 1. The scope of the claims must bear a reasonable correlation with the scope of enablement (In re Fisher, 166 USPQ 19 24 (CCPA 1970)). Without sufficient guidance, determination of

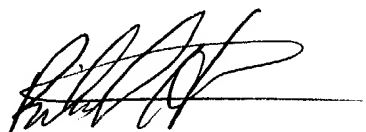
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having the desired biological characteristics is unpredictable and the experimentation left to those skilled in the art is unnecessarily, and improperly, extensive and undue. See *In re Wands* 858 F.2d 731, 8 USPQ2nd 1400 (Fed. Cir, 1988).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Richard G Hutson whose telephone number is (571) 272-0930. The examiner can normally be reached on 7:30 am to 4:00 pm, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapu Achutamurthy can be reached on (571) 272-0928. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Richard G Hutson, Ph.D.
Primary Examiner
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